

REMARKS

The above-identified application has been reviewed in light of the Office Action mailed on November 17, 2008. By the present amendment, the applicant has amended claims 1, 14, 15, and 23 for examination. It is respectfully submitted that the claims pending in the application, namely claims 1-15, 23 and 24, are fully supported by the specification, introduce no new matter, and are allowable over the cited art of record.

The Office Action rejected claims 14 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In response, claims 14 and 15 have been amended and Applicant respectfully requests withdrawal of this rejection.

Furthermore, lack of antecedent basis does not necessarily render a claim indefinite. See MPEP section 2173.05(e). A claim is indefinite when it contains words or phrases whose meaning is unclear. Although a lack of clarity could arise where the claim contains no earlier recitation or limitation, and where it would be unclear as to what element the limitation was making reference, if the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite.

The Office Action rejected claims 1-10, 13-15, 23, and 24 under 35 U.S.C. 103(a) as being unpatentable over Giampapa (5, 201, 728) (herein referred to as "Giampapa"). This rejection is respectfully traversed.

Presently, claim 1 recites a support structure comprising "an outer annular wall having a diameter; an inner annular wall spaced a radial distance inward of the outer annular wall and defining a space; an upper wall interconnecting the outer annular wall and the inner annular wall; and a lower wall spaced a distance from the upper wall and interconnecting the outer annular wall and the inner annular wall, the outer annular wall, the inner annular wall and the upper and lower walls defining an interior reservoir; and a wound closure material retained in

the reservoir and dispensable therefrom, the support structure containing the wound closure material until penetration by the staples."

Giampapa relates to an implantable multi-agent delivery system including a porous pod surface proportioned for subcutaneous implantation beneath the dermis of the skin. Giampapa does not teach or suggest the support structure recited in claim 1, including the wound closure material retained in the reservoir and dispensable therefrom upon penetration by staples. Giampapa does not suggest a puncturable reservoir that retains the therapeutic material until penetrated by staples. Giampapa purports to disclose a delivery system including a dome containing interior chambers which are in fluid communication with the pod's interior chambers. Bioactive agents are loaded into the dome and are released into the user's bloodstream through the pod's porous surface (column 3, line 18-21). The pod is porous and agents freely flow from one interior chamber into the bloodstream. The pod is not a reservoir, which retains the therapeutic material until penetrated by staples.

Furthermore, Claim 1 requires "an annular ring configured and adapted to substantially overlie the at least one annular arrangement of staples of the staple cartridge assembly" and Giampapa does not disclose an annular ring configured and adapted in this way. Giampapa's delivery system could not be used with a stapler having at least one annular arrangement of staples. Giampapa's system includes a dome for supplying the agents to the pod and could not be used with such a stapler as the staple cartridge and anvil assembly could not align over the dome and the pod to fire the staples and release the wound closure material. The dome of Giampapa would interfere with the operation of the stapler. Giampapa states, "an essential concept relative to the instant invention is that a plurality of bio-acting agents may be placed within compartments 32 of dome 26 and, after their exhaustion, or upon election of the physician, dome 26 may, through minor out-patient surgery, be removed from pod 10, refilled, and then re-secured to pod 10." (column 5, lines 12-18) The dome, which supplies the

therapeutic agent to the pod, is an essential concept is essential to the invention. The pod cannot deliver a therapeutic agent without the dome. The applicant respectfully asserts that the entire disclosure of Giampapa teaches away from the subject matter of claim 1 of the present application.

Therefore, it is respectfully requested that the rejection of claim 1 be withdrawn.

Claims 2-10 and 13-15 depend directly or indirectly upon claim 1 and, as these claims include all the limitations of claim 1, applicant asserts that the foregoing arguments apply equally to claims 2-10 and 13-15 and that the subject matter of each of these claims is patentable as a whole.

With respect to claims 4 and 5, the Office Action states that Giampapa discloses at least one removable support spoke (filaments of capillary mesh 17). The mesh structure of Giampapa is described as fluid transfer means, which are in fluid communication with pores 14. Nowhere does Giampapa suggest or teach that the mesh structure or even portions of the mesh are removable. Capillary mesh 17 is shown connected to inner circumference 28 in FIG. 2. Giampapa does not disclose how the mesh is intact nor even suggest that the capillary mesh is removable. With respect to claim 5, the Office Action states that Giampapa discloses a removable support spoke integrally connected to an extending diametrically across the inner annular wall and a central hub having a central axial opening formed therethrough. As stated above, Giampapa does not disclose or even suggest that the capillary mesh or a portion thereof is removeable. Furthermore, Giampapa's delivery system is not configured with a hub for receiving the shaft of an instrument and the mesh of Giampapa is not configured to receive a shaft of an instrument therethrough. As previously stated, claim 1 requires that the wound closure material is contained until released by the penetration of staples.

Furthermore, Claims 2-10, and 13-15 depend from independent claim 1 and incorporate all of the limitations of claim 1. For at least the reasons noted above with respect to claim 1,

claims 2-10, and 12-15 are not taught or suggested by Giampapa, and as a whole are patentable.

The Office Action has also rejected claims 23 and 24 under 35 U.S.C. 103(a) as being unpatentable over Giampapa. Claim 23 presently recites a support structure including, "an annular ring configured and adapted to substantially overlie the at least one annular arrangement of staples of the staple cartridge assembly, the annular ring including: an outer annular wall having a diameter; an inner annular wall spaced a radial distance inward of the outer annular wall and defining a space; an upper wall interconnecting the outer annular wall and the inner annular wall; and a lower wall spaced a distance from the upper wall and interconnecting the outer annular wall and the inner annular wall, the outer annular wall, the inner annular wall and the upper and lower walls defining an interior reservoir; a wound closure material retained in the reservoir, the support structure containing the wound closure material until penetration by the staples; and at least one removable support spoke integrally connected to and extending diametrically across the inner annular wall."

Claims 23 and 24 have been amended to require that the support structure contains the wound closure material until penetration by the staples. For the reasons discussed above in connection with claims 1, 4 and 5, applicant asserts that claims 23 and 24 are patentable over Giampapa.

The Office Action states that Giampapa discloses at least one removeable support spoke (filaments of capillary mesh 17). Nowhere does Giampapa suggest or teach that the mesh or even portions of the mesh are removeable. Nowhere does Giampapa suggest or teach a central hub with an opening configured and dimensioned to receive the shaft of a device. For at least the forgoing reasons, it is respectfully requested that claim 23 and 24 are allowable.

The Office Action has rejected claim 11 under 35 U.S.C. 103(a) as being unpatentable over Giampapa in view of Pilliar. (3,855,638) (herein referred to as "Pilliar"). Claim 11 depends

on claim 1 includes all of the limitations of independent claim 1. As discussed hereinabove, Giampapa does not teach or disclose an annular ring configured and adapted to substantially overlie the at least one annular arrangement of staples and wound closure material contained by the support structure until penetration by the staples. Pilliar is cited for a porous material comprising stainless steel or titanium. It is asserted that the porous material of Pilliar does not suggest a support structure that contains wound closure material until penetration by staples. Pilliar fails to disclose or suggest a support structure containing the wound closure material until penetration by the staples as recited in independent claim 1. Accordingly, Claim 11 is patentable over Giampapa in view of Pilliar and withdrawal of this rejection is respectfully requested.

The Office Action has rejected claim 12 under 35 U.S.C. 103(a) as being unpatentable over Giampapa in view of Schmitt et al. (3,739,773) (herein referred to as "Schmitt"). Claim 12 depends on claim 1 and includes all of the limitations of independent claim 1. As discussed hereinabove, Giampapa does not teach or disclose an annular ring configured and adapted to substantially overlie the at least one annular arrangement of staples and wound closure material contained by the support structure until penetration by the staples. Schmitt is cited for a porous bioabsorbable material. However, applicant asserts that Schmitt fails to disclose or suggest a support structure containing the wound closure material until penetration by the staples as recited in independent claim 1. Accordingly, claim 12 is patentable over Giampapa in view of Schmitt and withdrawal of this rejection is respectfully requested.


In view of the foregoing, it is respectfully submitted that all claims presently pending in the application, namely claims 1-15, 23 and 24, are in condition for allowance. Should the Examiner believe that a telephone or personal interview may facilitate resolution of any remaining matters, the Examiner is respectfully requested to contact the Applicant at the telephone number indicated below.

Appl. No. 10/516,435
Amendment dated January 30, 2009
Reply to Office Action mailed November 17, 2008

If any fee is due in connection with this response, the examiner is authorized to charge
deposit account number 21-0550 therefore.

Respectfully submitted,

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